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No. 85-664

IN THE
# Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER,
FOOD AND DRUG ADMINISTRATION,
*Petitioner,*

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
*Respondents.*

**ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT**

## BRIEF FOR RESPONDENTS IN OPPOSITION

William B. Schultz
(Counsel of Record)
Alan B. Morrison

Public Citizen Litigation Group
Suite 700
2000 P Street, N.W.
Washington, D.C. 20036
(202) 785-3704

*Attorneys for Petitioner*

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## QUESTION PRESENTED

May the Food and Drug Administration set levels for unavoidable food contaminants without providing any opportunity for public participation, where the Food, Drug and Cosmetic Act, 21 U.S.C. § 346, states that the FDA "shall promulgate regulations limiting the quantity" of such contaminants through a formal rulemaking proceeding?

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# BRIEF FOR RESPONDENTS IN OPPOSITION

## STATEMENT

This action challenges the method used by the Food and Drug Administration ("FDA") to regulate aflatoxins. Aflatoxins are a group of chemically related substances produced by molds which grow on corn and other agricultural products. They cause cancer in laboratory animals and are suspected of causing human liver cancer. App. 3a.[1] According to the National Academy of Sciences, aflatoxin B, the prevalent member of the strain, is "the most potent carcinogen known in laboratory animals."[2]

Although section 406 of the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. § 346, establishes a method for setting tolerances for aflatoxins and other unavoidable substances

[1] "App.__" refers to the Appendix to the Petition for a Writ of Certiorari; "Pet. at__" refers to the body of the petition.

[2] National Academy of Sciences, *Food Safety Policy, Scientific and Societal Considerations* (March 1979), p. 3—49.

which are unsafe, the FDA has issued only one tolerance in the 47 years since Congress adopted that provision. In every other instance, the agency has regulated these substances through informal action levels, which it sets and amends unilaterally, without any opportunity for public input, and without creating an administrative record that provides evidentiary support for its decision.

A. *Statutory Framework*

Section 402 of the FDC Act, 21 U.S.C. § 342, defines "adulterated" as that term pertains to food, and section 301(a), 21 U.S.C. § 331(a), prohibits the shipment of adulterated food in interstate commerce. Sections 402 and 406, 21 U.S.C. §§ 342, 346, divide substances which can cause food to be adulterated into several classifications and impose different standards on each category. The first category is poisonous or deleterious substances which are inherent in the food. Under section 342(a)(1), a food containing such a substance is adulterated only if the substance would "ordinarily render [the food] injurious to health."

A second category is poisonous or deleterious substances which are added to food, and these substances are regulated both by section 342(a)(1) and by section 346. Section 342(a)(1) sets a single standard for all added substances and declares that a food containing an added poisonous or deleterious substance is adulterated if the substance "may render [the food] injurious to health." This is a more rigorous standard than the "ordinarily" render injurious standard applicable to inherent substances.

However, in section 346, Congress subdivided added poisonous or deleterious substances into two additional categories. If the substance is intentionally added, the first sentence of section 346 declares that food containing it is "unsafe", without any requirement that there be a showing that it "may be injurious to health", and under section 342(a)(2) additives which are unsafe within section 346 are adulterated. In 1938, this provision covered pesticides, food additives, and color additives, although today these substances are largely regulated by separate licensing provisions in the FDC Act. *See* 21 U.S.C. §§ 346a, 348, 376.



Congress adopted a middle level standard for the second category under section 346—unavoidable additives, such as aflatoxin, mercury in fish, and pesticides which have been banned but still contaminate the soil. This provision represents a balance between the goal of eliminating poisonous and deleterious substances from food, and the recognition that some such substances are unavoidable. To implement this standard, in the first clause of section 346, Congress created an exception to the flat ban on added poisonous and deleterious substances, which applies if the substance is "unavoidable." However, in the statutory language which is the subject of this lawsuit, Congress provided that, for unavoidable contaminants:

> *the Secretary* [of Health and Human Services] *shall promulgate regulations* limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of [section 342(a)(2)].

21 U.S.C. § 346 (emphasis supplied). Thus, under this provision, a food is adulterated under section 342(a)(2) if it contains an avoidable, added poisonous or deleterious substance and no tolerance has been issued, or if the amount of the substance exceeds the established tolerance. Section 701(e) of the statute, 21 U.S.C. § 371(e), prescribes the method for setting tolerances: the FDA must use formal rulemaking, providing interested persons notice, an opportunity to comment, and an evidentiary hearing to resolve any material factual issues which are raised by formal objections.

B. *Regulation of Aflatoxin*

Although section 346 uses the word "shall" to describe the Secretary's obligation to promulgate regulations, the FDA has never issued a regulation establishing the limits of aflatoxin in food.[3] Instead, in 1965, the FDA established an "action level" of

[3] The Secretary has delegated virtually all her duties under the FDC Act to the Commissioner of the Food and Drug Administration. 21 C.F.R. § 5.10(a)(1985).

30 parts per billion ("ppb") for aflatoxin, which was the lowest level of contamination which could be detected under technology existing at that time. 39 Fed. Reg. 42748, 42749 (Dec. 6, 1974). In 1969, the agency reduced the action level to 20 ppb, where it has remained ever since. *Id.*

The term "action level" appears in neither the FDC Act nor the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551, *et seq.* Instead, action levels are a method of regulation created solely by the FDA. The agency does not issue the action levels for aflatoxin and other unavoidable contaminants as regulations, nor does it publish proposed action levels for comment in the Federal Register. Instead, it simply announces new action levels once they are final. Moreover, since 1938, with one exception, the agency has used action levels rather than the procedures prescribed by the sections 346 and 371(e) to regulate unavoidable, added substances which it has determined cause food to be adulterated.

Action levels were initially publicized through press releases or other announcements, and it was not until 1977 that the agency published an administrative manual containing all existing action levels and indicated that any future action levels would be published in final form in the Federal Register, with a notice inviting public comment. 21 C.F.R. § 109.4(b)(2). However, the FDA does not even assume an obligation to respond to public comments, and it reserves the right to change its action levels at any time, also without allowing the public an opportunity to participate. *Id.*

The regulation of aflatoxin provides an example of how the FDA implements this regulation. In 1978, the FDA deviated from its longstanding prohibition against "blending" contaminated foods, by allowing corn containing aflatoxin at levels greater than 20 ppb to be blended with less contaminated corn, in order to obtain a mixture under the 20 ppb limit. The decision was issued in a January 31, 1978 letter to a private firm and was not published in the Federal Register until April 4, 1978. 43 Fed. Reg. 14122.

In the fall of 1980, the FDA again permitted blending of corn containing aflatoxin above the action level, and again it waited



several months to publish this decision. *See* 46 Fed. Reg. 7447 (Jan. 23, 1981). In response to this announcement, respondents filed the instant lawsuit, challenging both the agency's use of action levels and its policy of permitting blending. In 1983, while the case was pending in district court, the agency once again announced that it had decided to permit blending of corn contaminated with aflatoxin. 48 Fed. Reg. 53175 (Nov. 25, 1983). Pursuant to the FDA's regulations, 21 C.F.R. § 109.4(b)(2), respondents submitted objections to the final decision on December 16, 1983, but the agency never responded.

Although the FDA issues action levels without complying with the formal rulemaking requirements of the FDC Act or the notice and comment requirements of the APA, it treats action levels as though they had the same force as regulations. Thus, for purposes of enforcing the FDC Act's prohibition on adulterated food, the FDA prosecutes persons who ship corn with aflatoxin above the 20 ppb action level, and, more importantly, it also explicitly permits the shipment of corn containing less than 20 ppb aflatoxin. For these reasons, an action level is not simply the equivalent of a decision not to prosecute a manufacturer for a single violation of the FDC Act. Instead, it represents a binding commitment that the agency will permit the sale of products containing contaminants below the action level.

C. *Proceedings Below*

Respondents are two consumer organizations and an individual consumer. Their complaint raised two issues in addition to the claim that the FDA is required to use sections 346 and 371(e) of the FDC Act to set limits for unavoidable contaminants. Thus, respondents alleged that, even if section 346 does not require the FDA to issue tolerances, action levels are "rules" within section 2(c) of the APA, 5 U.S.C. § 551(4), because they are binding on the FDA and have a future effect on the agency and the public. Therefore, at a minimum, the FDA is required to publish action levels as proposed rules and provide an opportunity for public comment. 5 U.S.C. §§ 551(5), 553. *See, e.g., American Bus Ass'n v. United States,* 627 F.2d 525, 529 (D.C. Cir. 1980)("[i]f it appears that a so-called policy statement is in purpose or likely effect one

that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of substantive law" to which the rulemaking provisions of the APA apply, *quoting Guardian Federal Savings & Loan Ass'n v. Federal Savings & Loan Insurance Corp.*, 589 F.2d 658, 666-67 (D.C. Cir. 1978)); *Nader v. Civil Aeronautics Board*, 657 F.2d 453, 456 (D.C. Cir. 1981) ("mandatory language, which narrowly circumscribes the Board's discretion to suspend air fares. . . plainly constitutes a substantive rule"). Respondents' third claim was that the FDA's policy of permitting blending of corn contaminated with aflatoxin violates the FDC Act and the agency's own regulations. *See* pp. 4-5, *supra.*

The district court rejected all three arguments, but the court of appeals reversed the lower court's ruling on the section 346 claim. In a unanimous opinion by Judge Starr, the court held that "the intent of Congress is abundantly clear in requiring the formal issuance of tolerances, rather than permitting agency reliance solely on informal action levels." App. 6a. In doing so, the court gave great weight to the language in the statute: the "presence of the critical word 'shall' plainly suggests a directive to the Secretary to establish a tolerance." *Id.* The FDA had argued that the phrase in the statute "to such extent as [the Secretary] finds necessary for the protection of the public health" qualifies the word "shall" and makes the use of formal tolerances optional. The court rejected that argument on the ground that it is "clear from the structure of the sentence at issue here" that the phrase "simply does not modify the pivotal word 'shall.'" *Id.* at 7a.

Finally, the court held that none of the cases cited by the FDA supported a different result. It found that they all involved the agency's power to enjoin the shipment of adulterated products rather than whether the agency may grant "permission to ship without the establishment of tolerances." *Id.* at 13a. In summary, the court held that "[t]he interpretation accorded the Act by the FDA flies in the teeth of Congress' clear intent and, under long established principles of administrative law, must therefore be rejected." *Id.* at 6a. Since the court concluded that the FDA is required to issue tolerances under section 346, it did not reach respondents' claim that the FDA had also violated the notice and



comment requirements of the APA. *Id.* at 15a. It remanded the blending issue to the district court for consideration in light of its decision. *Id.* at 15a-16a.

Petitioner subsequently filed a petition for rehearing, with a suggestion that the court hear the case *en banc.* The panel denied the petition, and the court denied the suggestion, with a notation that no member had requested a vote on whether the case should be heard by the full court. *Id.* at 18a, 19a.

## REASONS FOR DENYING THE PETITION

There is no dispute about the fact that aflatoxin is a poisonous or deleterious substance which is "added" to corn within the meaning of sections 342 and 346 of the FDC Act. Therefore, the only legal issue raised by the petition is whether the FDA may issue informal action levels to permit the sale of corn containing aflatoxin, instead of using the formal tolerance procedures provided in sections 346 and 371(e).

As we demonstrate below, none of the grounds advanced by the FDA justifies granting the petition. First, the court of appeals correctly relied on the language of the statute, and the court correctly held that section 346 directs the FDA to establish tolerances for unavoidable contaminants. Second, the cases from other circuits relied on by petitioner raise the distinctly separate issue of whether the FDA may prosecute manufacturers whose products exceed an action level, even though the agency has not issued a tolerance pursuant to section 346. Since none of those cases involved the opposite side of the coin—the issue of whether the FDA may use action levels to sanction products containing the contaminant—there is no conflict in the circuits which justifies review by this Court.

Finally, the case does not raise an issue of sufficient importance to justify consideration by this Court. As the FDA points out (Pet. at 16), there are only eight substances which have action levels, and there is no support in the record for the agency's claim (*id.* at 7) that it would take "years, if not decades" to issue regulations setting tolerances under section 346. Moreover, the hearing requirements applicable to formal tolerances are similar to the

right to a hearing which Congress has granted to manufacturers of drugs, food additives, and other products regulated by the FDC Act. In light of the policies of both the FDC Act and the APA, the agency's current practice of regulating unavoidable contaminants without any public participation is simply unacceptable, and therefore the decision of the court of appeals enjoining it from continuing this practice should be allowed to stand.

1. The FDA admits that the interpretation of section 346 adopted by the court of appeals is "entirely rational and plausible" (Pet. at 8). Indeed, the lower court's interpretation is the most natural and direct reading of the statute. Thus, section 346 declares that, if an added substance is unavoidable:

> the Secretary *shall* promulgate regulations limiting the quantity therein or thereon *to such extent as he finds necessary for the protection of public health*

(emphasis supplied). The FDA argues that the second italicized portion of the quotation modifies the word "shall", and therefore that section 346 merely authorizes the Secretary to issue tolerances, if he chooses to do so. The flaw in this argument is that it has no support in the structure of the sentence. If Congress had intended the qualifying language to modify "shall", it would have placed the qualification directly after that word. By placing that phrase where it did, Congress indicated that it intended the words "to the extent . . . necessary for the protection of public health" to provide the measure of protection to be used by the FDA in establishing the appropriate tolerance level. Thus, the word "shall" directs the FDA to issue regulations, section 371(e) directs it to use formal rulemaking procedures, and the second italicized clause states that the levels chosen must be those "necessary for the protection of public health."

Second, under the FDA's construction, the statute would have had precisely the same meaning if Congress had used the phrase "is authorized to" in place of the word "shall." In fact, S. 5, the bill adopted by the Senate, used that phrase. S. 5, 75th Cong., 1st Sess. § 15(a) (1937). However, several of the bills which had previously been introduced in the House of Representatives used



"shall" to describe the FDA's duty under the tolerance-setting section. *See* H.R. 6110, 73rd Cong., 1st Sess. § 11(a) (1933); H.R. 8316, 73rd Cong., 2d Sess. § 10(a) (1934). Thus, in considering the Senate bill, the House Committee on Interstate and Foreign Commerce could have adopted either of two very different alternatives. The House committee chose "shall", and therefore it amended the Senate bill to state that the Secretary "shall promulgate regulations" limiting the quantity of unavoidable contaminants. House Committee on Interstate and Foreign Commerce, 75th Cong., 1st Sess., S.5 § 406(a) (Confidential Committee Print No. 2, 1937). This language was ultimately enacted, without change, as section 346 of the FDC Act, and in section 371(e) Congress also required the FDA to adhere to the formal rulemaking requirements when it issued those regulations. This legislative history demonstrates that Congress explicitly drafted the FDC Act to *require* the FDA to limit the amount of unavoidable contaminants in food through regulations adopted pursuant to section 371(e).

For the first time in this litigation, the FDA's petition argues that respondents' interpretation of the Act makes the portion of section 342(a)(1) applicable to added substances superfluous. Pet. at 9. However, this simply is not so, since even if section 346 is mandatory, section 342(a)(1) will continue to apply to poisonous or deleterious additives for which the FDA has not yet issued a tolerance. Thus, on the day the new statute became effective, the FDA did not have tolerances in place. Similarly, in subsequent years, poisonous or deleterious added substances have been identified, which, even under respondents' construction of the statute, cannot be regulated through tolerances until sufficient time has elapsed for the agency to comply with the procedures in section 371(e). For this reason, in section 342(a)(1) of the Act, Congress retained the portion of the Food and Drugs Act of 1906 applicable to added substances, even though in section 346 it directed the agency to issue tolerances for those substances.[4]

[4] The 1906 Act used language which is almost identical to the first clause of section 342(a)(1). It defined food as adulterated if "it contain[s] any added poisonous or other added deleterious ingredient which may render such article injurious to health." 1906 Federal Food and Drugs Act § 7, 34 Stat. 768 (repealed by 21 U.S.C. § 392).

Thus, under respondents' construction of the statute, the portion of section 342(a)(1) which applies to added substances is not superfluous because it may be used whenever a new, added contaminant is discovered.

In fact, it is the FDA's construction of the statute that would make section 346 superfluous. According to the petitioner, the sole purpose of section 346 is to authorize the agency to issue regulations which formalize its action levels. However, even without section 346, the agency would have this authority, since section 701(a) of the Act authorizes it to "promulgate regulations for the efficient enforcement of [the] Act." 21 U.S.C. 371(a). Therefore, under petitioner's own standards of statutory construction, in order to avoid redundancy with section 371(a), section 346 should be construed as requiring the FDA to issue formal tolerances for added poisonous or deleterious substances which are unavoidable.

The pesticide amendments of 1954 also provide no support for the FDA's construction of section 346. As the FDA points out, Congress removed pesticides from the coverage of section 346, and enacted a new provision, 21 U.S.C. § 346a, which establishes somewhat less formal procedures for setting tolerances for pesticide residues in raw agricultural products. These procedures actually support respondents' construction of section 346 in two respects. First, the enactment of the 1954 law suggests that Congress had concluded that the FDA did not then have the authority to use less formal procedures, such as action levels, to regulate pesticides. Second, Congress did not amend section 346, but instead retained that section and the procedures applicable under section 371(e) for substances other than pesticides. Thus, the only reasonable conclusion to draw from the pesticide amendments is that Congress intended the requirements of 346 to continue to apply to all added substances, except pesticides, which would be covered by the less formal procedures in the new law.[5]

[5] This is further demonstrated by testimony given on behalf of the National Canners Association, which appears immediately after the letter quoted in the Petition (*see* Pet. at 11 n.5.):

*Congressman O'Hara*: This has nothing to do with—this proposed legislation has nothing in the way of an effect upon section 406 [21 U.S.C. § 346] of the present law. This is true, is it not?

*Mr. Austern* [on behalf of the National Canners Association]: That is true.

*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 2d Sess. 32 (1954). Similarly the FDA's argument that Congress in 1954 concurred with the agency's construction of section 346 is rebutted by the Report of the House Committee on Interstate and Foreign Commerce which noted that "[t]here are no provisions for such exemptions or temporary tolerances in the present law." H.R. Rep. No. 1385, 83d Cong., 2d Sess. 6 (1954).



Having agreed that the court of appeals' interpretation of section 346 is as plausible as the agency's (Pet. at 8), the FDA is left to argue that the court did not accord proper deference to its interpretation of the statute. However, the deference ordinarily accorded an agency's construction of a statute should be tempered where, as is the case here, its construction would lessen the burdens which would otherwise be placed upon it. Just as courts have generally not deferred to agencies in interpreting the procedural requirements of the APA, the FDA's interpretation of section 346 should be given little, if any, deference. In any event, the court of appeals correctly held in this case that the FDA's construction of section 346 is inconsistent with the plain meaning of the statute, and thus the degree of deference accorded is immaterial.

2. Contrary to petitioner's assertions, there is no division among the courts of appeals regarding the correct interpretation of section 346. In *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979), the court held that the FDA may use its authority under section 342(a)(1) to initiate enforcement proceedings to enjoin the shipment of corn containing aflatoxin in excess of the agency's 20 ppb action level. In ruling for the FDA, the Fifth Circuit stated that "the FDA either may adopt formal regulations, 21 U.S.C. § 346, or may litigate the alleged violations on a case-by-case basis." *Id.* at 151. Relying on this statement, the FDA argues that *Boston Farm Center* is inconsistent with the D.C. Circuit's decision in the instant case. Pet. at 13.

However, the Fifth Circuit was not presented with the question of whether the FDC Act requires the FDA to use formal rulemak-

ing, instead of action levels, in establishing permissible levels of unavoidable contaminants such as aflatoxin. It only held that the statute prohibits unavoidable contaminants, even where the agency has not established a tolerance, and that the agency may enforce the statutory requirements on a case-by-case basis under section 342(a)(1). The court did not decide the issue in this case, which is whether the FDA may *exempt* contaminants below a specified level without complying with the requirements of sections 346 and 371(e) of the FDC Act.

*United States v. Goodman,* 486 F.2d 847 (7th Cir. 1973), is distinguishable for the same reason. The court held that the Environmental Protection Agency could prohibit the distribution of fish with *any* DDT residue. Therefore, the defendants were not "harmed" where the agency had declined to issue a formal tolerance but had adopted an action level which gave "them the opportunity to continue to operate if they can distribute fish with 5 or less parts per million of DDT residue." *Id.* at 855. Thus, there is no conflict between the D.C. Circuit's opinion in this case and the decision of any other circuit.

3. The FDA has overstated the adverse implications of the lower court's decision. If the decision stands, the status of foods with respect to section 346 will be precisely the same as it was when the FDC Act became effective. The FDA will be obligated to issue tolerances for substances covered by section 346, but, in the meantime, it may regulate those substances under sections 342(a)(1) and 342(a)(2). Thus, there is no merit to the agency's argument (Pet. at 16) that its ability to regulate unavoidable contaminants will somehow be hampered if it is required to promulgate formal tolerances.

This same practical result has been reached by courts in construing other parts of section 342 as well. Thus, in interpreting section 342(a)(3), which prohibits "filthy, putrid, or decomposed substance[s]"in food, the Fifth Circuit has recognized that this section "sets a standard that if strictly enforced, would ban all processed food from interstate commerce" because a "scientist with a microscope" could find such a substance "in almost any canned food we eat." *United States v. 484 Bags, More or Less,* 423



F.2d 839, 841 (1970), *quoting United States v. 1500 Cases, Etc.,* 236 F.2d 208, 210-11 (7th Cir. 1956). Nevertheless, "the majority, in fact almost unanimous, rule is that the Act confers the power to exclude from commerce all food products which contain in any degree filthy, putrid or decomposed substances", although such "harsh consequences. . . are tempered by discretion given the Secretary." 423 F.2d at 839 (citations omitted). Any "harsh consequences" of the court of appeals' decision here could be tempered in the same manner.

There is also no support for the argument that the process of establishing tolerances under section 346 will impose a severe administrative burden on the agency. As the FDA points out (Pet. at 16), the agency has action levels for only eight substances which are covered by section 346. Moreover, in many respects, the procedures required by sections 346 and 371(e) are similar to the notice and comment procedures mandated by the APA. The only significant difference is that section 371(e) requires the agency to provide an opportunity for an evidentiary hearing where there are disputed issues of material fact.

In comparable circumstances, the FDC Act already provides for a hearing on decisions pertaining to prescription drugs, food additives, and a variety of other products regulated by the agency. 21 U.S.C. §§ 348(f), 355(e), 376(d).[6] Even though thousands of products fall under the jurisdiction of these provisions, the hearing requirement has not paralyzed the FDA because in most cases the agency denies the application for a hearing and issues a summary decision, a procedure which was upheld by this Court in *Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620-22 (1973). Therefore, it is incorrect to assume that the court of appeals' decision would require the FDA to hold hearings even for all of the eight added substances for which it currently has action levels.

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[6] *See* Merrill, *Regulating Carcinogens in Food: A Legislator's Guide to the Food Safety Provisions of the Federal Food, Drug, and Cosmetic Act,* 77 Mich.L.Rev. 171, 208 (1978) ("[t]he statutorily prescribed process for approving or withdrawing approval of a food additive is as complex as that required for the establishment of tolerances under section 406 [21 U.S.C. § 346]").

Although it has no statutory foundation, as a policy matter the agency's argument that action levels are temporary measures might carry weight if it were correct in claiming that they are "used when changes in the capabilities of good manufacturing practices are expected or when the results of ongoing studies might provide significant new data or other data that might render a tolerance obsolete." Pet. at 5; *see also* Pet. at 16. Although this is an accurate description of the criteria contained in the agency's regulations and policy statements,[7] the case of aflatoxin graphically illustrates that the agency has never followed this policy. Thus, the action level for aflatoxin has been constant since 1969, *see* p. 4, *supra*, and there are no ongoing technological changes or uncertainties about scientific data which justify a temporary standard. The fact that the agency has issued only one tolerance in 47 years demonstrates beyond any reasonable dispute that it views action levels as a permanent substitute for tolerances under section 346.

The FDA correctly points out that, like any regulation or licensing decision, a formal tolerance could not be revoked or amended as easily as an informal action level. However, this same argument would lead to the conclusion that formal procedures need not be used to license new drugs and food additives, or other products regulated by similar provisions of the FDC Act. Whatever the merits of that argument, it is plainly not the method which Congress chose to regulate unavoidable contaminants, and therefore it does not support the agency's claim that Congress intended to give it the flexibility to regulate section 346 substances without issuing regulations.

In any event, the FDA totally ignores the benefits of using regulations. Under its current practice, it must prove that corn contaminated with aflatoxin above 20 ppb is unsafe each time that it brings a lawsuit for violation of an action level. *See, e.g., United States v. Boston Farm Center, Inc., supra.* On the other hand, if it had issued a formal tolerance, it would have to show

[7] 21 C.F.R. § 109.6(b)-(c); *see also* 42 Fed Reg. 53814, 52817 col. 1-3 (September 30, 1977); 39 Fed. Reg. 42743, 42745 col. 3 (December 6, 1974).



only that the level of aflatoxin exceeded the tolerance; any challenge to the tolerance would have to be made directly, and not as a defense to a court action. Thus, while the agency would have to use resources in setting the tolerance, it would save resources when prosecuting companies which have violated its regulations. Moreover, by permitting public participation, the agency would make more informed decisions regarding the regulation of substances which are poisonous or deleterious when added to foods.

In summary, while there are policy arguments which can be made on both sides of this issue, Congress has chosen to require the agency to use tolerances in regulating section 346 substances. Therefore, any changes in the statute should be made by the legislature and not by the FDA or the courts.

## CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

William B. Schultz
(Counsel of Record)
Alan B. Morrison

Public Citizen Litigation Group
Suite 700
2000 P Street, N.W.
Washington, D.C. 20036
(202) 785-3704

Attorneys for Respondents

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